

REMARKS

The remarks herein are responsive to the Office Action dated September 26, 2007. Upon entry of the foregoing amendments, Claims 1-2 and 4-28 remain pending. Claim 3 has been canceled without prejudice and Applicant reserves the right to pursue the subject matter of this canceled claim at a later date. Claims 1, 4, 8, 12, 13, 22, and 25 have been amended. New Claims 29-40 have been added.

Rejection of the Claims 35 U.S.C. § 112

Claims 12, 13, and 25 stand rejected under 35 U.S.C. § 112, as failing to particularly point out and distinctly claim the subject matter of the invention. Applicant has amended Claims 12 and 25, as shown above, and respectfully submits that Applicant has adequately addressed these rejections. Accordingly, Applicant respectfully requests withdrawal of the § 112 rejections of Claims 12, 13, and 25.

Rejection of the Claims Under 35 U.S.C. § 102

Claims 1, 6-8, 10-12, 15-20, 24, and 26-28 stand rejected under 35 U.S.C. § 102 as being anticipated by Pilliar (U.S. Patent No. 3,855,638). Applicant has amended Claims 1, 8, and 12, as shown above.

The prosthesis in Pilliar includes a coating with “pore and pore size distributions substantially uniform from the coating substrate interface to the surface of the coating.” See Pilliar, col. 3 at lines 27-30. Pilliar emphasizes the significance of using pore sizes at least as large as 50 µm (or be no less than 20 µm for soft tissue growth). See Pilliar, col. 3 at lines 52-54, 61-63; col. 6 at lines 23-25, 43-48. The structure of the coating in Pilliar can be produced by sintering metallic powder to an implant surface. See Pilliar, col. 7 at lines 29-40. Pilliar further notes that different pore sizes can be provided at different positions on the implant. See Pilliar, col. 8 at lines 23-26.

Claim 1

Claim 1, as amended above, recites *inter alia*: an open-pored biocompatible surface layer for an implant comprising an “open-pored surface layer comprising a shallow roughening in the sub-micrometer range.” Applicant respectfully submits that Pilliar fails to disclose, teach, or suggest all of the limitations of amended Claim 1. For example, as discussed during the Examiner interview, Pilliar does not disclose or teach, among other things, an open-pored surface

layer with a shallow roughening in the sub-micrometer range. The prosthesis of Pilliar has only one level of structure, that being the open-pored structure produced by sintering a metallic powder to the implant surface. As noted in paragraph [0006] of the above-identified application, the roughness of the erstwhile metallic powder in Pilliar is smoothed out as a result of surface diffusion during the sintering process taught in Pilliar. Thus the surface of Pilliar cannot have a roughening in the sub-micrometer range.

Moreover, Applicant respectfully submits that Pilliar teaches away from the features of amended Claim 1. For example, Pilliar notes the significance of pores at least 50 μm large. This teaches away from structure smaller than 50 μm , let alone structure in the sub-micrometer range.

In view of the above, Applicant respectfully submits that amended Claim 1 is allowable over Pilliar. Claims 2, 4-7 depend from amended Claim 1 and are therefore likewise allowable over Pilliar, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features, not taught, or suggested by the cited art. Similarly, Claims 26-28 depend from the aspects of Claim 1 discussed here, and are therefore also likewise allowable over Pilliar, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features, not taught or suggested by the cited art.

Claim 8

Claim 8, as amended above, recites *inter alia*: a method of producing an implant comprising “applying at least one layer of a biocompatible metal or an alloy thereof to a virgin surface of the implant, to produce an implant surface comprising an open-pored structure with a porosity in range of between about 20% and 85%; and producing a surface micro-structure on the implant surface.” Applicant respectfully submits that Pilliar fails to disclose, teach, or suggest all of the limitations of amended Claim 8. As discussed above, Pilliar has only one level of surface structure, does not teach a surface micro-structure less than 50 μm , and further teaches away from a surface micro-structure less than 50 μm . Thus, Applicant respectfully submits that amended Claim 8 is allowable over Pilliar. Claims 9-25 depend from amended Claim 8 and are therefore likewise allowable over Pilliar, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features, not taught, or suggested by the cited art. For example, currently amended Claim 22 recites *inter alia*:

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“etching of the implant surface.” Pilliar does not disclose, teach, or suggest etching an implant surface.

Rejection of the Claims Under 35 U.S.C. § 103

Claims 1, 8, 11-14, 22, and 23

Claims 1, 8, 11-14, 22, and 23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Shimamune. Applicant has amended Claims 1, 8, 12, 13, and 22.

Shimamune discloses a process for providing a titanium composite having a porous surface. The process of Shimamune prepares a mixture of titanium and magnesium powders and a binder. Shimamune sinters this mixture onto the implant surface and removes the magnesium.

Claim 1, as amended above, recites *inter alia*: an open-pored biocompatible surface layer for an implant comprising an “open-pored surface layer having a shallow roughening in the sub-micrometer range.” Applicant respectfully submits that Shimamune fails to disclose, teach, or suggest all of the limitations of amended Claim 1. For example, as discussed during the Examiner interview, Shimamune does not disclose or teach, among other things, an open-pored surface layer having a shallow roughening in the sub-micrometer range. The surface layer produced by Shimamune has only one level of structure, that being an open-pored structure produced by sintering a metallic powder to the implant surface. Notably, as discussed above, the metallic powder is smoothed as a result of surface diffusion during the sintering process taught in Shimamune. Thus like the implant in Pilliar, the open-pores produced by Shimamune cannot have any roughening. Thus, Applicant respectfully submits that amended Claim 1 is allowable over Shimamune.

Claim 8, as amended above, recites *inter alia*: a method of producing an implant comprising “applying at least one layer of a biocompatible metal or an alloy thereof to a virgin surface of the implant, to produce an implant surface having an open-pored structure with a porosity in a range of between about 20% and 85%; and producing a surface micro-structure on the implant surface.” Applicant respectfully submits that Shimamune fails to disclose, teach, or suggest all of the limitations of amended Claim 8. As discussed above, the process in Shimamune produces only one level of structure, and thus does not produce both an open-pored structure *and* a surface micro-structure. Thus, Applicant respectfully submits that amended

Claim 8 is allowable over Shimamune. Claims 11-14, 22, and 23 depend from amended Claim 8 and are therefore likewise allowable over Shimamune, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features, not taught, or suggested by the cited art.

Claim 2

Claim 2 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Pilliar in view of Branemark (U.S. Pat. No. 4,330,891). Applicant has amended Claim 1, from which Claim 2 depends.

Branemark discloses an element for implantation in body tissue, particularly bone tissue “consisting of a biologically flawless material with a porous, i.e., micro-pitted surface.” Branemark, col. 2 at lines 3-6. The Branemark surface has micro-pits created by oxidation for example. See Branemark, col. 4 at lines 8-19. The size of these pits preferably range from 10 to 1000 nm. See Branemark, col. 2 at lines 38-44. Branemark further discloses implant shape features such as through-holes in the implant for tissue in-growth, as well as depots of agents beneficial to the healing process. See Branemark, Claims 2, 8-9. These larger holes and depots are features of the shape of the implant and not features of the implant surface, as indicated by claims including an element that includes “at least one” hole, depot, groove, etc. Applicant notes that a feature of an implant surface such as, e.g., a hole implies that the implant comprises many holes scattered about said surface and not only “at least one.”

Claim 2 depends from amended Claim 1, which recites *inter alia*: an open-pored biocompatible surface layer for an implant comprising an “open-pored surface layer having a shallow roughening in the sub-micrometer range.” Applicant respectfully submits that, alone or in combination with Pilliar, Branemark fails to teach or suggest all of the elements of amended Claim 1. Like Pilliar for example, Branemark teaches only one level of surface structure.

Additionally, the “porous” layer of Branemark is not an open-pored surface, but instead a micro-pitted surface. See Branemark, col. 2 at lines 5-6 (“with a porous, i.e., micro-pitted surface”). Thus, Applicant respectfully submits that Branemark does not teach or suggest, among other things, an “open pored surface layer,” as recited, among other features, in Claim 2. In contrast, the non-limiting embodiment described in paragraph [0032] of the above-identified specification, upon which amended Claim 1 reads, describes one embodiment of an “open-pored

structure" as having "undercuts and cavities . . . so that bone that is growing in can engage behind the porous surface layer and, by that means, ensure optimum anchoring."

Applicant further submits that Branemark and Pilliar teach away from each other. As discussed above, Branemark stresses a pore size less than 1000 nm. In contrast, Pilliar stresses a pore size greater than 50 µm (50,000 nm), stating that "[i]n order for the porous adherent coating to be able to sustain bone, or other hard tissue growth, it is essential that the interstitial pore size exceed 50 microns." Pilliar, col. 3 at lines 51-56 (emphasis added). As noted by the Supreme Court's decision in *KSR Int'l. v. Teleflex, Inc.*, a finding of nonobviousness is more likely when the prior art references teach away from a combination of elements. *See KSR Int'l. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740 (2007). Accordingly, Applicant submits that one of ordinary skill in the art would not combine Pilliar and Branemark because the references teach away from each other, and that the Examiner has therefore not established a *prima facie* case of obviousness.

Additionally, the combination of Pilliar and Branemark do not teach or suggest all of the features of Claim 2 because, as noted above, while Pilliar and Branemark each describe different surface structures for an implant, neither suggests creating a surface layer with two levels of structure. As discussed above, the depots, grooves, and larger holes in Branemark are not surface features but features of the implant shape. Thus, Pilliar and Branemark do not disclose, teach, or suggest a surface with more than one level of surface structure. Thus, Applicant submits that an implant surface with two levels of structure constitutes a nonobvious advance over the prior art and meets a long felt need for superior implantation surfaces. Further, Applicant submits that the combination of an open-pored structure and a shallow roughening in the sub-micrometer range presents a further nonobvious advance over the prior art.

In view of the above, Applicant respectfully submits that Claim 2 is allowable over Pilliar in view of Branemark, not only because it depends from an allowable base claim, but also because it recites a unique combination of features not taught or suggested in the cited art.

Claim 3

Claim 3 has been canceled, but the limitations of Claim 3 have been amended to Claim 1, from which Claim 3 depended. Claim 3 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Pilliar in view of Steinemann (U.S. Pat. No. 5,456,723).

Steinemann discloses a metallic implant anchorable to bone tissue for replacing a broken or diseased bone. The surface of the implant in Steinemann includes pits with a magnitude of 2 μm or less, created with a reducing acid. See Steinemann, col. 3 at lines 7-12, 23-25, 46-54. Additionally, the pits created by the reducing acid can be superimposed upon a larger micro-roughness created by either acid treatment or sandblasting. See Steinemann, col. 3 at lines 7-12, 46-54. The micro-roughness is generally described as having a maximum peak-to-valley height (“ R_s ”) of 10-30 μm . See Steinemann, col. 3 at lines 28-31, 50-54; col. 4 at lines 3-4; col. 6 at Table 1, lines 31-33; Claims 1-3, 6. The micro-roughness further is further described to have a roughness spacing (RS) of 1 to 5 μm , “correspond[ing] to the preferable mean diameter of the pits.” See Steinemann, col. 3 at lines 30-33; col. 6 at Table 1; Claims 1, 3, 6.

Amended Claim 1 recites *inter alia*: an “open-pored surface layer having a shallow roughening in the sub-micrometer range.” As discussed above, Applicant respectfully submits that Pilliar does not disclose, teach, or suggest all of the elements of amended Claim 1. Applicant further submits that Steinemann does not disclose, teach, or suggest all of the elements of amended Claim 1. For example, Steinemann does not teach an open-pored surface. As described in Steinemann, the acid treatment produces “pits.” Further, Applicant submits that the sandblasting that can produce the “microroughness” in Steinemann would also produce pits. Thus, Steinemann discloses a surface structure that only includes pits, but does not disclose, among other things, an “open-pored surface layer having a shallow roughening in the sub-micrometer range.” As discussed above, an open-pored surface layer allows substantially more in-growth than a pitted layer.

Further, Steinemann discloses superimposing two surface structures that are substantially the same. In regard to shape, both acid treatment and sandblasting produce pits. In regard to size, as shown above, both the pits and micro-roughness are in the micrometer range and Steinemann particularly describes the size of the micro-roughness to “correspond to the preferable mean diameter of the pits.” Applicant further notes that Examples I and III in Steinemann comprise only one level of surface structure, as the surface is created in only one step. Therefore, Applicant submits that the pits and the “microroughness” of Steinemann are substantially similar in both size and shape. Thus, Applicant respectfully submits that

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Steinemann does not disclose, among other things, “open-pored surface layer having a shallow roughening in the sub-micrometer range,” as recited, among other features in amended Claim 1.

Applicant further notes, as discussed above, that Pilliar teaches away from surface features of size less than 50 µm, such as those in Steinemann. As noted by the Supreme Court’s decision in *KSR Int’l. v. Teleflex, Inc.*, a finding of nonobviousness is more likely when the prior art references teach away from a combination of elements. *See KSR Int’l. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740 (2007). Accordingly, Applicant submits that Pilliar teaches away from the combination with Steinemann, and that the Examiner has therefore not established a *prima facie* case of obviousness.

In view of the above, Applicant respectfully submits that amended Claim 1 is allowable over Pilliar in view of Steinemann. Claim 3 depends from amended Claim 1 and is therefore likewise allowable over Pilliar and Steinemann, not only because it depends from an allowable base claim, but also because it recites a unique combination of features not taught or suggested by the cited art.

Claims 4, 5, 9, 21, and 25 stand rejected under U.S.C. § 103(a) as unpatentable over either Pilliar or Shimamune, in view of other cited art. Applicant respectfully submits that the arguments recited above overcome these rejections. Moreover, Applicant submits that Claims 4, 5, 9, 21 and 25 are allowable, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features not taught or suggested by the cited art.

Claim 27

Claim 27 corresponds to the claim as amended in the Preliminary Amendment submitted on December 22, 2004, but which Applicant notes does not appear on the published application. Applicant requests that the amendment to Claim 27 made in the Preliminary Amendment be entered.

New Claims

Applicant has added new independent Claims 33 and 37 and new dependent Claims 29-32, 34-36, and 38-40. Independent Claim 33 recites, *inter alia*: producing a surface micro-structure on the open-pored implant surface. As discussed above, Applicant submits that such

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subject matter is not disclosed by the cited art. Thus, Applicant respectfully submits that Claim 34 is allowable over the cited art. Independent Claim 37 recites, *inter alia*: “a surface micro-structure applied to the open-pored implant surface.” As discussed above, Applicant submits that such subject matter is not disclosed by the cited art. Applicant further submits that Claims 29-32, 34-36, and 38-40 depend from allowable independent Claims 8, 26, 33, and 37 and are therefore likewise allowable, not only because they depend from allowable base claims, but also because each of these claims recites a unique combination of features, not disclosed, taught, or suggested by the cited art.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
11/722,697	A METHOD OF SURFACE FINISHING A BONE IMPLANT	12/22/2005

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a

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claim should not be understood to base patentability on that portion or that the limitation discussed is essential or critical; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although changes to the claims have been made, no acquiescence, disclaimer or estoppel is intended or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. Applicant may not have presented in all cases, arguments concerning whether the applied references can be properly combined or modified in view of the deficiencies noted above, and Applicant reserve the right to later contest whether the cited references can be properly combined.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve such issue promptly.

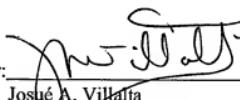
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 1/28/08

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AMEND

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